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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,967	02/27/2004	Joseph Anthony Gatto	8725R2R	9429

27752 7590 06/25/2008  
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EXAMINER
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PAGONAKIS, ANNA

ART UNIT	PAPER NUMBER
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1614

MAIL DATE	DELIVERY MODE
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06/25/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/789,967	GATTO, JOSEPH ANTHONY	
	<b>Examiner</b>	<b>Art Unit</b>	
	ANNA PAGONAKIS	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 11-18 and 20-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-18 and 20-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1 sheet; 5/9/2008</u> .                                       | 6) <input type="checkbox"/> Other: _____                          |

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### **DETAILED ACTION**

Applicant's reply filed 5/9/2008 has been received and entered into the present application.

Claims 11-18, 20-25 remain pending. Accordingly, claims 1-10, 19 have been cancelled, claims 11, 14 have been amended, and claims 21-25 have been added.

As reflected by the attached, completed form PTO/SB/08A (one page total), the Examiner has considered the cited reference.

Rejections and objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

### **Change of Examiner**

The examiner assigned to the instant application has changed. The new examiner is Anna Pagonakis. Contact information is provided at the end of the Office Action.

### **Information Disclosure**

Applicants have stated that Examiner's assertion that a search report is not a patent literature is not understood. Search reports are not published documents and therefore have no date of publication and for these reasons are not considered as prior art documents and thus not considered during examination.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11-18, 20-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term “from about,” “at least about” and “less than about” are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, one of ordinary skill in the art would be reasonably apprised of the scope of the invention, because one of skill will not be able to determine which term is in control. The claims lack clarity as to whether "from" (a lower limit) or "about" (broadening limitation, both higher and lower) controls the metes and bounds of the phrase "from about." Regarding "at least" (a lower limit) or "about" (broadening limitation, both higher and lower) it is unclear what controls the metes and bounds of the phrase “at least about.” Regarding "less than (a lower limit) or "about" (broadening limitation, both higher and lower) it is unclear what controls the metes and bounds of the phrase "less than about."

Claims 11-18, 20-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. The term “from about,” “at least about” and "less than about” are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention, because one of skill will not be able to determine which term is in control. The claims lack clarity as to whether "from" (a lower limit) or “about” (broadening limitation, both higher and lower) controls the metes and bounds of the phrase "at

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least about." Regarding "less than (a lower limit) or "about" (broadening limitation, both higher and lower) it is unclear what controls the metes and bounds of the phrase "less than about."

*Applicant's Response*

Applicants allege that such claim terms are commonly used in defining numerical ranges, especially in the chemical arts. Further, Applicant's submit that one of ordinary skill in the art would understand the scope of the invention from these claim terms based on the common use of these terms in claim drafting, the nature of the chemical invention, and the specification of the present invention.

*Response to Applicant's Arguments*

Applicant's arguments have been carefully considered in their entirety, but fail to be persuasive in establishing error in the propriety of the present rejection.

Examiner contends that the definition of "about" or "at least" or "from" is not provided in the instant disclosure. Therefore, it is impossible for one to know with certainty which numerical ranges are applicable.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-18, 20-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Osborne et al. (US 6,716,441) and Lin et al. (US 2002/0115968, of record) in view of Gatto et al. (US 6,793,930).

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Osborne et al. teach an effective delivery of a therapeutic skin care active to the skin via a novel release composition which is preferably incorporated into a dispensing means. Many types of disposable absorbent articles, such as diapers, training pants, adult incontinence devices, sanitary napkins, panty liners and the like are available to absorb and contain urine and other bodily exudates (column 1, lines 1-18). Petrolatum is typically used to provide a long-lasting coating (column 1, lines 66-67). An article, such as those just described, with a composition comprising niacinamide, panthenol, chitosan, and vitamin C. Skin actives include calamine, cysteine hydrochloride, racemic methionine, sodium bicarbonate, vitamin c (column 5, lines 33-38), and talc (column 15, line 55). Suitable solvents include propylene glycol and glycerine (column 16, line 28).

Lin et al. teach chitosan in skin care absorbing article (see abstract) a diaper (see diagram front page).

Gatto et al. teach a skin care composition (see abstract) having the characteristics wherein the particle size of the skin care agent is less than 100 microns (see col 11. lines 35-50) results from milling (see col. 16, lines 34), and the carrier of petrolatum (see col. 16, lines 45-49) wherein the composition can further comprise vitamins (see col. 24, line 57). Finally, the use of a diaper is taught in Figure 1.

Given that niaciamide, panthenol, chitosan and vitamin C is a composition known to be used on absorbent articles, one of ordinary skill in the art would have a reasonable expectation of success that combining the cited art would in fact teach the invention as claimed. The combined cited art teaches the claimed invention, therefore one of ordinary skill in the art would be motivated to make a sanitary napkin or a diaper that has all these properties because each of the cited art has incorporated the claimed invention in whole or in part to a product that is used as a hygiene skin care or an absorbent article for the skin. Thus motivating one of ordinary skill in the art to combine and optimize.

“[W]hen a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the

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combination is obvious”. KSR v. Teleflex, 127 S.Ct. 1727, 1740 (2007)(quoting Sakraida v. A.G. Pro, 425 U.S. 273, 282 (1976). “[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious”, the relevant question is “whether the improvement is more than the predictable use of prior art elements according to their established functions.” (Id.). Addressing the issue of obviousness, the Supreme Court noted that the analysis under 35 USC 103 “need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” KSR v. Teleflex, 127 S.Ct. 1727, 1741 (2007). The Court emphasized that “[a] person of ordinary skill is... a person of ordinary creativity, not an automaton.” Id. at 1742.

**Note: MPEP 2144.04 [R-1]** Changes in Sequence of Adding Ingredients: Ex parte Rubin , 128 USPQ 440 (Bd. App. 1959) (Prior art reference disclosing a process of making a laminated sheet wherein a base sheet is first coated with a metallic film and thereafter impregnated with a thermosetting material was held to render *prima facie* obvious claims directed to a process of making a laminated sheet by reversing the order of the prior art process steps.). See also In re Burhans, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (selection of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results); In re Gibson, 39 F.2d 975, 5 USPQ 230 (CCPA 1930) (Selection of any order of mixing ingredients is *prima facie* obvious.).

### Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In*

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*re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 11-18, 20-25 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent Application No. 10/992383. Although the conflicting claims are not identical, they are not patentably distinct from each other. The reasons are as follows:

The copending application recites the steps of the instant claims wherein it provides a carrier system identified as petrolatum, as in the instant claim, having a temperature of at least 35 degrees C, comprising a chitosan having the same properties used as a sanitary napkin in claims 20 and 22 of the copending application.

In view of the foregoing, the copending application claims and the current application claims are obvious variations.

### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANNA PAGONAKIS whose telephone number is (571)270-3505. The examiner can normally be reached on Monday thru Thursday, 9am to 5pm EST.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AP  
6/18/2008

/Ardin Marschel/  
Supervisory Patent Examiner, Art Unit 1614